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09/897,309	07/02/2001	Robert B. Odell	P-3946C1C1	1739

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EXAMINER
HUYNH, LOUIS K

ART UNIT	PAPER NUMBER
3721	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/897,309	Applicant(s) ODELL ET AL.	
	Examiner Louis K. Huynh	Art Unit 3721	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 July 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. The terminal disclaimer filed on November 25, 2002 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 6,189,292 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1, 3-18, 33, 34, 37, and 38 are rejected under 35 U.S.C. 102(a) as being anticipated by Lawecki et al. (US 5,687,542).

Lawecki discloses a method of producing a container/syringe barrel including the steps of: forming a container/syringe barrel (126) in a forming device (18), transferring the container/syringe barrel to an enclosure (10) of class 100 environment (col.3, lines 5-10), cleaning the container/syringe barrel by directing a stream of filtered air toward the container/syringe barrel to keep contaminants from setting on the container/syringe barrel (col.4, lines 22-24), lubricating the container/syringe barrel (col.8, lines 19-25), supplying and lubricating tip caps and stoppers (col.8, lines 22-25), optional steps of filling the container/syringe barrel (col.8, lines 25-29) to form a prefilled syringe, placing the container/syringe barrel/prefilled syringe in a holder (68) (col.7, lines 17-21), enclosing the

container/syringe/prefilled syringe barrel in a second container (128) (col.7 lines 25-28), and removing the container/syringe barrel/prefilled syringe from the enclosure (col.7, lines 35-43).

Regarding the step of sterilizing the containers as recited in claim 1, Lawecki discloses a step of sterilizing the containers with sterilizing gas in the molding module (column 3, lines 43-48).

Regarding claims 3, 6, 10-11 and 16-17, Lawecki discloses that the container (126) can be formed from either plastic (preferred embodiment) or glass through a process that generates enough heat (i.e. heating a glass tube at one end to form a flange, heating the glass tube for shaping the other end to receive a cannula needle, heating the glass barrel to an annealing temperature, etc.) to render an article substantially free from contaminants (col.3, lines 38-43).

Regarding claims 4, 7, 15 and 18, the process disclosed by Lawecki can be modified to include filling the container with a desired substance and assemble steps, i.e. lubricating the syringe barrel and stopper, applying tip cap, applying stopper, etc. (col.8, lines 19-29) to complete the assembly of a prefilled syringe (col.2, lines 31-38).

Regarding claims 8-9 and 13-14, Lawecki discloses a HEPA filter (50) including an independent blower (col.4, lines 33-41) drawing the air from a class 100,000 environment and delivering a laminar stream of air flow into the enclosure (10) of class 100 environment fully enveloping the syringe (col.4, lines 44-50) to keep contaminants from setting on the syringe (col.4, lines 22-24). Lawecki further discloses that the enclosure of class 100 environment is operated at a positive minimum of 0.5" w.c. pressure relative to the ambient pressure of the class 100,000 environment in which the enclosure is placed (col.4, lines 51-54). Lawecki also

discloses an overhead fixture (114) including an ion bar anti-static assemblies (col.7, lines 9-10) for reducing static charge of the syringe.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 3, 10 and 11 are alternatively rejected under 35 U.S.C. 103(a) as obvious over Lawecki et al. (US 5,687,542) in view of Logothetis (US 4,521,237).

To the extent that applicants do not agree that the container is formed from glass, then Logothetis discloses a method for forming a glass syringe barrel (1) wherein an upper end of a glass tube (2) is heated to a pliable state and is flared to formed a flange (col.3, lines 57-62), see Figs.1 & 2; the lower end of the glass tube is also heated to a pliable state for shaping the lower end to receive a cannula needle (3) (col.5, lines 8-14), see fig.5; the syringe barrel assembly is then heated to an annealing temperature (col.4, lines 24-27). Lawecki discloses that any process for forming a container that generates enough heat to render an article substantially free of contaminants can be applied in the invention. Therefore, it would have been obvious to one with an ordinary skill in the art at the time the invention was made to have modified the method of Lawecki by having added a glass forming station for performing the steps of forming a glass syringe barrel, as taught by Logothetis, so that both glass and plastic syringes can utilize the same enclosure (10) of class 100 environment in the subsequent processes of producing a prefilled syringe.

Regarding claims 10 and 11, the exact temperature range of heating glass to a pliable state for shape forming and the temperature range of annealing depend on the type of glass and are known by those skilled in the art (applicants' specification page 19, lines 19-27). Therefore, the temperature range for heating the glass tube is considered to be about 760°C to 1100°C, and the temperature range for heating the glass tube to an annealing temperature is considered to be about 560°C.

6. Claims 7, 15 and 33 are alternatively rejected under 35 U.S.C. 103(a) as obvious over Lawecki et al. (US 5,687,542) in view of Jurgens, Jr. et al. (US 4,628,969).

To the extent that applicants do not agree with the general disclosure of the lubricating and filling steps in the method disclosed by Lawecki, then Jurgens, Jr. discloses a process for producing a prefilled plastic syringe having a cylindrical side wall, receiving end (28) and outlet nozzle (24), see Figures 1 & 2 for example, including the steps of: coating a syringe barrel (22), a tip cap (26) and a stopper (30) with silicone solution (col.3, lines 10-16); applying the tip cap to close outlet nozzle (col.4, lines 16-17); filling the syringe barrel with a desired substance (col.4, lines 19-21) through the receiving end; then applying the stopper to the receiving end (col.4, lines 22-25). Therefore, it would have been obvious to an ordinary skilled person in the art at the time the invention was made to have modified the method of Lawecki et al. by having provided the steps of filling, as taught by Jurgens, Jr. et al., in order to fill the syringe through the receiving end.

7. Claim 37 is alternatively rejected under 35 U.S.C. 103(a) as obvious over Lawecki et al. (US 5,687,542) in view of Smith et al. (US 5,597,530).

To the extent that applicant does not agree with the general disclosure of the lubricating and filling steps in Lawecki method, then Smith discloses a process for producing a prefilled plastic syringe having a cylindrical side wall (24), receiving end (22) and outlet nozzle (20), see Figure 1 for example, including the steps of: inserting a stopper (16) into the syringe barrel (12) through the receiving end (col.5, lines 48-50); filling the syringe barrel with a desired substance through the outlet nozzle (col.6, lines 9-11); then applying a tip cap (14) to the outlet nozzle (col.6, lines 20-21). Therefore, it would have been obvious to an ordinary skilled person in the art at the time the invention was made to have modified the method of Lawecki by having provided the steps of filling, as taught by Smith, in order to fill the syringe through the outlet nozzle.

8. Claims 19-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawecki et al. (US 5,687,542) in view of Logothetis (US 4,521,237).

Lawecki et al. discloses a method of producing a prefillable glass syringe assemblies including the steps of: forming a glass syringe (126) in a glass forming device (col.3, lines 38-43), transferring the glass syringe to an enclosure (10) of class 100 environment (col.3, lines 5-10), cleaning the glass syringe by directing a stream of filtered air toward the glass syringe to keep contaminants from setting on the glass syringe (col.4, lines 22-24), lubricating the glass syringe (col.8, lines 19-25), transferring the glass syringes to a packaging station (58), placing the glass syringes in a holder (68) to form an array of eight glass syringes (col.7, lines 17-21),

enclosing the array in a second container (128) (col.7 lines 25-28), which meet all of applicant claimed subject matter except for the detailed process of forming a glass syringe.

However, Logothetis discloses a process for forming a glass syringe assembly on automatic machinery (col.3, lines 40-43), wherein an upper end of a glass tube (2) is heated to a pliable state and is flared to formed a flange (col.3, lines 57-62), see figs.1 & 2; the lower end of the glass tube is also heated to a pliable state for shaping the lower end to receive a cannula needle (3) (col.5, lines 8-14), see fig.5; the glass syringe assembly is then heated to an annealing temperature (col.4, lines 24-27). And, Lawecki discloses that any process for forming a container that generates enough heat to render an article substantially free of contaminants can be applied.

Therefore, it would have been obvious to an ordinary skilled in the art at the time the invention was made to have modified the method of Lawecki by having provided a glass forming station for performing the steps of forming a glass syringe assembly, as taught by Logothetis, so that glass syringes are produced as another preferred embodiment.

Regarding claim 21, the range of the heating and annealing temperature are known by an ordinary skilled in the art depending on the type of glass (applicant's specification page 19, lines 19-27); therefore the heating temperature is considered to be about 760°C to 1100°C and the annealing temperature is considered to be at least 560°C.

Regarding claims 26-27, Lawecki discloses a HEPA filter (50) including an independent blower (col.4, lines 33-41) drawing the air from a class 100,000 environment and delivering a laminar stream of air flow into the enclosure (10) of class 100 environment. Lawecki further discloses that the enclosure of class 100 environment is operated at a positive minimum of 0.5"

w.c. pressure relative to the ambient pressure of the class 100,000 environment in which the enclosure is placed (col.4, lines 51-54).

Regarding claims 30-31, Lawecki discloses a plastic molding device enclosed within the enclosure (10) (col.3, lines 25-31). Similarly, the modified method of Lawecki for producing glass syringes would have the glass forming device enclosed within the enclosure (10) of class 100 environment as well.

9. Claims 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawecki et al. (US 5,687,542) in view of Jurgens, Jr. et al. (US 4,628,969).

Lawecki discloses a method of producing a filled syringe which meets all of applicant's claimed subject matter except for the step of sterilizing the prefilled syringe.

However, Jurgens, Jr. discloses a method of producing prefilled sterile plastic syringes including the step of sterilizing a prefilled syringe (20) after the step of filling and the step of applying the stopper (30) and prior to the step of packaging the prefilled syringe (column 3, lines 33-43).

Therefore, it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have modified to method of Lawecki by having provided the step of sterilizing the prefilled syringe, as taught by Jurgens, Jr., in order to maintain the cleanliness and sterility of the syringe prior to packaging.

10. Claims 39 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lawecki et al. (US 5,687,542) in view of Smith et al. (US 5,597,530).

Lawecki discloses a method of producing a filled syringe which meets all of applicant's claimed subject matter except for the step of sterilizing the prefilled syringe.

However, Smith et al. discloses a method of producing prefilled sterile plastic syringes including the step of sterilizing a prefilled syringe (12) after the step of filling and the step of applying the tip cap (14) (col.6, lines 26-44) and prior to the step of packaging the prefilled syringe.

Therefore, it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have modified to method of Lawecki by having provided the step of sterilizing the prefilled syringe, as taught by Smith, in order to maintain the cleanliness and sterility of the syringe prior to packaging.

Response to Arguments

11. Applicant's arguments filed 11/25/02 (paper No. 8) have been fully considered but they are not persuasive.

Applicants contend that Lawecki fails to teach or suggest enclosing the container in a second container and sterilizing the container and thus does not anticipated claim 1 as amended. This is not found persuasive because Lawecki does disclose the step of sterilizing the container (col. 3, line 43-48) and thus anticipates the claimed invention as recited in the amended claim 1.

Applicants further contend that Lawecki does not teach or suggest the step of delivering a tip cap to the environmentally controlled area and air cleaning the tip cap in the environmentally controlled area as recited in claims 33 and 37. This is not found persuasive because the method

of Lawecki utilizes laminar stream of air flow to clean fabricated articles including the syringes and/or tip seals that are introduced into the enclosure (10) of class 100 environment.

Regarding the traversal with respect to claim 19, although neither Lawecki nor Logothetis expressly discloses annealing a glass syringe barrel at a temperature of at least 500°C, the specific annealing temperature is well within the knowledge of a skilled person in the art, and therefore it would have been obvious to a person with an ordinary skill in the art, at the time the invention was made, to have annealed the glass syringes barrel at a temperature of at least 500°C.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis K. Huynh whose telephone number is (703) 306-5694. The examiner can normally be reached on M-F from 9:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached on (703) 308-2187. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3579 for regular communications and (703) 308-7769 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1148.

LH
January 22, 2003

JOHN SIPOS
PRIMARY EXAMINER